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0200-0023.20  
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Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BILLING-MEDEL et al.

Serial No.: 09/099,823

Group Art Unit: Unassigned

Filing Date: June 19, 1998

Examiner: Unassigned

Title: REAGENTS AND METHODS USEFUL FOR DETECTING DISEASES OF  
THE BREAST

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TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449 and copies of the cited references. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 7/14/98

By: [Signature]  
Roberta L. Robins  
Registration No. 33,208

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Atty No. 6120.US.P1  
0200-0023.20  
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In Re Application of:

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Serial No.: 09/099,823

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Title: REAGENTS AND METHODS USEFUL FOR DETECTING  
DISEASES OF THE BREAST

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INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. A completed Form PTO-1449 listing the references identified below accompanies this paper. Copies of the references which were of record in related application serial number 08/879,354 and from which the present application claims priority under 35 U.S.C. §120 are not included pursuant to C.F.R. §1.98(d). The references not already made of record in the 08/879,354 application are enclosed.

Applicants would appreciate the Examiner's initialling and returning the form to indicate that the references have been reviewed and made of record in the present application. The information includes:

Blaker et al., "Molecular Cloning of Human Von Ebner's Gland Protein, A Member of the Lipocalin Superfamily Highly Expressed in Lingual Salivary Glands," *Biochimica et Biophysica Acta*. 1172:131-137 (1993);

Jacobs et al., "Clinical Use of Tumor Markers in Oncology," *Curr. Prob. Cancer* 299-350 (1991);

Pantel et al., "Methods for Detection of Micrometastatic Carcinoma Cells in Bone Marrow, Blood and Lymph Nodes," *Onkologie* 18:394-401 (1995);

Redl et al., "cDNA Cloning and Sequencing Reveals Human Tear Prealbumin to be a Member of the Lipophilic-Ligand Carrier Protein Superfamily," *J. Biol. Chem* 267(28):20282-20287;

Redl et al., Annotation for "Prealbumin," Accession No. M90424;

Schwartz et al., In: *Cancer: Principles & Practice of Oncology* 1 4th Edition, 531-542 (1993), Philadelphia, PA: J/B/ Lippincott Co.; and

Annotation for "Von Ebner's Gland Protein Precursor (Veg Protein)," Accession No. 401346 October 1, 1996.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or

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USSN: 09/099,823  
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enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 7/14/98 By: Roberta L. Robins  
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Submitter John Russell

Marker ID BS124



AI-1

## Information from annotation

## Entrez document

LOCUS 401346 176 aa 01-OCT-1996  
 DEFINITION VON EBNER'S GLAND PROTEIN PRECURSOR (VEG PROTEIN) (TEAR PREALBUMIN)  
 (TP) (TEAR LIPOCALIN) (LIPOCALIN-1).  
 ACCESSION 401346  
 PID g401346  
 DBSOURCE SWISS-PROT: locus VEGP\_HUMAN, accession P31025  
 class: standard.  
 created: Jul 1, 1993.  
 sequence updated: Jul 1, 1993.  
 annotation updated: Oct 1, 1996.  
 xrefs: embl accession X62418, gi: 37661, embl accession X67647, gi:  
 313856, genbank accession L14927, gi: 307518, genbank accession  
 M90424, gi: 184458  
 xrefs (non-sequence databases): MIM 151675, PROSITE PS00213  
 KEYWORDS TRANSPORT; SIGNAL; LIPOCALIN.  
 SOURCE human.  
 ORGANISM Homo sapiens  
 Eukaryotae; mitochondrial eukaryotes; Metazoa; Chordata;  
 Vertebrata; Eutheria; Primates; Catarrhini; Hominidae; Homo.  
 REFERENCE 1 (residues 1 to 176)

## Literature abstract

Biochim Biophys Acta 1172: 131-7 (1993) [93176795]

Molecular cloning of human von Ebner's gland protein, a member of the lipocalin superfamily highly expressed in lingual salivary glands.

M. Blaker, K. Kock, C. Ahlers, F. Buck & H. Schmale

Institut für Zellbiochemie und klinische Neurobiologie, Universität Hamburg, Germany.

Von Ebner's glands (VEG) are small lingual salivary glands. Their ducts open into trenches of circumvallate and foliate papillae, thus influencing the milieu where the interaction between taste receptor cells and sapid molecules takes place. The major secretions of human VEG is a protein with a molecular mass of 18 kDa. The human VEG protein crossreacts with antibodies raised against the rat VEG protein, indicating sequence similarity between the rat and human VEG proteins. This was subsequently confirmed by N-terminal protein sequencing. A cDNA clone, isolated from a human VEG library, contained an insert of 735 bp including an open reading frame that encodes the human VEG protein of 176 amino acids. Comparison of the human and rat VEG proteins revealed an overall identity of 60%. Immunocytochemistry, in situ hybridization and in vitro translation studies demonstrated the human VEG protein to be highly and exclusively expressed in VEG. The VEG proteins are members of the lipocalin protein superfamily and, together with the rat odorant binding protein II, they constitute a new subfamily.

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